4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Issues in the Design of Clinical Trials of Antibacterial Drugs for the Treatment of Non-Cystic Fibrosis Bronchiectasis; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop focusing on the design of clinical trials of antibacterial drugs for the treatment of non-cystic fibrosis (non-CF) bronchiectasis. This public workshop is intended to provide information for, and gain perspective from, health care providers, patients and patient advocacy organizations, academia, and industry on various aspects of the design of clinical trials. The input from this public workshop will useful in developing topics for further discussion.

Date and Time: The public workshop will be held on September 7, 2012, from 8 a.m. to 3:30 p.m.

Location: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel's phone number is 301-589-0800. Seating is limited and available on a first-come, first-served basis.

Contact Persons: Christine Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6204, Silver Spring, MD 20993-0002, 301-796-1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email your registration information (including name, title, firm name, address, telephone, and fax number) to bronchiectasisworkshop@fda.hhs.gov. Those without access to the Internet may call 301-796-1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner (see Contact Persons) at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM after submission of a Freedom of Information request. Written requests should be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet (http://www.fda.gov/Drugs/NewsEvents/ucm305463.htm) approximately 45 days after the workshop.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop focusing on scientific considerations in the design of clinical trials of antibacterial agents for the treatment of non-CF bronchiectasis. Discussions will focus on natural history; patient populations for enrollment in clinical trials; current standard of care and unmet need; clinical trial endpoints, including exacerbation and patient-reported outcomes; and clinical trial design elements, including duration of treatment and patient followup.

FDA encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Dated: August 10, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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